



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,187	03/24/2004	Joseph S.M. Peiris	V9661.0078	4585

7590 03/06/2006

Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas
New York, NY 10036-2714

EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,187

Applicant(s)

PEIRIS ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 4-10 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 4, 2005.

Priority

For amended claim 13, the effective date is 4/23/2003. Although the hSARS virus CCTCC-V200303 was described in earlier applications, one could not conceptualize the full genus of primers derived from the viral sequence until the full structure of the genome was disclosed on 4/23/2003. It is noted that partial sequences were disclosed earlier; however, these partial sequences are not representative of the full range of primers deduced from the full genomic sequence. Therefore, the first adequate written description of the genus is 4/23/2003.

Claim Rejections - 35 USC § 102

Claim 13 remains rejected under 35 U.S.C. 102(a) as being clearly anticipated by Peiris et al (Lancet 361:1319-1325, published online April 8, 2003) or Drosten et al (New England Journal of Medicine 348:1967-1976, published online April 10, 2003) or Ksiazek et al (New England Journal of Medicine 348:1953-1966, published online April 10, 2003). The examiner does not agree with applicant's argument that the effective date for this claim is 4/2/2003, for the reasons discussed above.

Claim 3 remains rejected under 35 U.S.C. 102(e) as being anticipated by McSwiggen et al WO 2004/092383. Applicant argues that McSwiggen lists a large

number of sequences and does not disclose which sequences are useful as a probe. Applicant is claiming a nucleic acid molecule; McSwiggen teaches a nucleic acid molecule which meets each and every limitation recited in the claim. A reference does not need to teach the same intended use for a chemical compound, and does not need to teach any use at all, in order to anticipate the compound. The fact that McSwiggen teaches many additional chemical compounds does not negate the finding that McSwiggen teaches a compound meeting the limitations of claim 3 before the effective date of claim 3.

Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al US 2001/0053519. These claims are drawn to an isolated nucleic acid consisting of at least 10 contiguous nucleotides of a recited sequence. Fodor teaches the formation of an array which contains every single isolated 10-mer (see Example 2, beginning on page 12). This complete set of 10-mers necessarily and inherently includes the 10-mers of claims 22-24.

Claim Rejections - 35 USC § 103

Claim 21 remains rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al WO 2004/092383 for reasons of record. Applicant essentially repeats the same arguments as for the 102 rejection over McSwiggen. However, since all claim 21 requires is the nucleic acid in a container, and containers are very conventional, it is maintained that it would have been obvious to place any or all of the 3,400 sequences of McSwiggen in a container. This rejection could be obviated if the claim were

amended to require the kit to contain additional components for a PCR assay, since McSwiggen does not teach or suggest using the nucleic acid as a PCR primer.

Claim Rejections - 35 USC § 112

Claims 11-19, 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. For example, in claim 11, the preamble states "detecting the presence of the hSARS virus in a sample," but claim 11 does not mention the sample any active step or correlate "detecting in the nucleic acid" the stated purpose of detecting a virus. It is suggested that step (a) change "of the hSARS virus" to "from the sample", and add step "(c) wherein said detecting indicates the presence of the hSARS virus in the sample."

This rejection was not necessitated by applicant's amendment, therefore this action is nonfinal.

Double Patenting

Claims 1-3, 11-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over at least claims 18, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139, 146, 158, 159, 166-170 of copending Application No. 10/808121. In addition to the reasons given in the previous Office action, the instant claimed nucleic acids are not patentably distinct from nucleic acids of the copending application because the instant seqs 2471-2476 would hybridize under stringent conditions to a nucleic acid encoding the V200303 genome as required by copending claims. Also the nucleic acids of the instant seqs 2474-2476 are part of SEQ I% or its complement in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 29, 31, 44 of copending Application No. 10/895064. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is overlapping scope between the primers derived from V200303 and CoV-HKU1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 1, 2, 20 are allowable, assuming resolution of provisional double patenting issues.

Claims 11, 12, 14-18, 25-30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action; again, assuming resolution of provisional double patenting issues.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/2/06


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER